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9. 510(k) Summary.

9.1. Submitter's identification.

- Industrial & Medical Design, Inc.
  2570 Corporate Pl., Suite E104
  Monterey Park, CA 91754

- Contact person: Yevgeniy Kuklin
  President

- Date Summary Prepared: September 26, 2003

9.2. Submitted device name.

- Trade name: LucentLite

- Classification name: Laser Surgical Instrument,
  21 CFR § 878.4810

9.3. Identification of predicate devices.

- Company: Altus Medical, Inc.
- Device: Family of Altus Medical CoolGlide Aesthetic Lasers
  510(k) K022226, K003202

- Company: CoolTouch Corporation
- Device: CoolTouch Nd:YAG Laser System
  510(k) K014035

- Company: Sciton, Inc.
- Device: Profile 1320 Laser System
  510(k) K022466

9.4. Device description.

The LucentLite Laser is comprised of the following main components:
- Console (including laser, electronics, cooling system, and software);
- Control panel;
- Permanently attached fiberoptic-coupled handpiece;
- Skin cooling device;
- Foot pedal;
- Remote interlock connector.

9.5. Intended use of the device.

The LucentLite Laser is intended for use in surgical and aesthetic applications requiring selective photothermolysis of target chromophores in soft tissue in the medical specialties of general and plastic surgery and dermatology:

9.6. Rationale for Substantial Equivalence.

The LucentLite Laser shares the same general indications for use, similar design features, and functional features as predicated devices.
Therefore, the technological differences between LucentLite Laser and predicated devices do not raise any new issues of safety, effectiveness, or performance of the product. We believe that LucentLite is substantially equivalent to the above legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Angela Mallery
President
Industrial & Medical Design, Inc.
2570 Corporate Place, Suite E104
Monterey Park, California 91754

Re: K033072
Trade/Device Name: LucentLite
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 9, 2004
Received: January 12, 2004

Dear Mr. Kuklin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

5. Indication for Use Statement.

Applicant: Industrial & Medical Design Inc.

510(k) Number: K033072

Device Name: LucentLite.

Indications for Use:
The LucentLite Laser is intended for use in surgical and aesthetic applications requiring selective photothermolysis of target chromophores in soft tissue in the medical specialties of general and plastic surgery and dermatology:

1064 nm:
- To effect stable long-term, or permanent* hair reduction through selective targeting of melanin in hair follicles.
- For the removal of unwanted hair.
- For coagulation and hemostasis of vascular lesions.
- For Incision/excision of soft body tissues in dermatology.
- For soft tissue general surgery applications: skin incision; tissue dissection; excision of external tumors and lesions; complete or partial resection of internal organs, tumors, lesions; tissue ablation; vessel coagulation.

* Permanent hair reduction is defined as a long-term stable reduction in the number of hairs regrowing after treatment regimen.

1320 nm:
- For the treatment of periorbital and perioral wrinkles.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033072

Prescription Use ✓ OR Over-The-Counter-Use__
(Per 21 CFR 801.109) (Optional Format 1-2-96)